

Remarks

Applicants request reconsideration on the merits of the above-referenced patent application.

I. Claim amendments

This amendment adds claims 21-28. Thus, claims 6-28 are pending. Claims 6, 7, 9, 11, 12, and 20 have been amended. Applicants submit that the amendments and new claims do not introduce new matter. Specifically:

Applicants have amended claims 6, 7, 9, 11, 12, and 20 to characterize the recited live bacterial vaccine as being a live attenuated bacterial vaccine. This amendment is supported by, for example, page 1, lines 22-28; and the claims as originally filed.

New claims 21 and 22 are supported by Applicants' specification at, for example, page 1, lines 22-30; page 2, lines 17-28; and Examples 1-3 on pages 7-9.

New claim 23 recites the conditions listed in, for example, pending claim 7, and is supported by Applicants' specification at, for example, page 4, line 3 to page 5, line 29.

New claim 24 recites the conditions listed in, for example, pending claim 12, and is supported by Applicants' specification at, for example, page 4, line 3 to page 5, line 29.

New claims 25-28 recite mammals listed in, for example, pending claims 13-16, respectively, and are supported by Applicants' specification at, for example, page 4, line 3 to page 5, line 25.

Applicants reserve the right to pursue any canceled subject matter and/or any other subject matter disclosed in this application in one or more divisional and/or continuation applications.

II. Response to the double patenting rejections

Claims 6-11 and 17-20 have been rejected under the judicially-created doctrine of obviousness-type double patenting in view of claims 1-4 of U.S. Patent 6,682,745.

Applicants submit that this rejection is premature because claims 6-11 and 17-20 have not yet been found to be otherwise allowable. Once the claims in this application have been found to be otherwise allowable, Applicants will further address the merits of this rejection and/or file a terminal disclaimer.

Claims 6-8 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent 6,120,775.

Applicants submit that this rejection is premature because claims 6-8 have not yet been found to be otherwise allowable. Once the claims in this application have been found to be otherwise allowable, Applicants will further address the merits of this rejection and/or file a terminal disclaimer.

III. Written description rejection

Claims 6-20 have been rejected under 35 U.S.C. 112 (first paragraph) as failing to comply with the written description requirement for including new matter. More specifically, these claims have been rejected for reciting a live bacterial vaccine without further limitation. Applicants request withdrawal of this rejection.

At the outset, Applicants respectfully submit that this subject matter is fully supported by their specification. Applicants believe that this subject matter is supported by their specification at, for example, page 1, lines 20-21. Applicants believe that this amendment also is supported by Examples 1-3 on pages 7-9, which illustrate the use of four different live bacterial strains, including both attenuated and virulent strains.

Nevertheless, in an effort to expedite prosecution of this patent application, Applicants have amended claims 6, 7, 9, 11, 12, and 20 so that all of claims 6-20 now recite a live *attenuated* bacterial vaccine. Applicants submit that their specification provides sufficient written description for the term "live attenuated bacterial vaccine." This is particularly true when their specification is viewed in combination with the knowledge that existed in the art at the time of their earliest priority filing. That knowledge, for example, includes various publicly available live attenuated vaccines, such as those that Applicants listed in their June 22, 2006 Amendment D on pages 9-12. That non-exhaustive list alone demonstrates that the preparation of attenuated bacteria having immunogenic properties from non-attenuated bacteria was part of the common knowledge in the art on the priority date. Although Applicants' Example 1 focuses on *S. equi* strains, any of the publicly available strains also could have generally been used. Applicants, in fact, note this in their specification. *See, e.g.*, page 1, lines 25-28. Applicants should not be penalized for omitting specific descriptions of

such vaccines and their preparation. After all, as noted in MPEP §2164.01, a patent "preferably omits" anything that is already well known in the art.

Applicants also submit that their specification provides sufficient written description for the subject matter recited in their new claims 21-28. Those claims do not recite a method that comprises the administration of a vaccine *per se*. Instead, they recite submucosal administration of live attenuated bacteria wherein any abscess and/or lesion formation at the site of the submucosal administration is less in total size than the abscess and/or lesion formation that would occur if the bacteria were instead administered intramuscularly or intradermally. Thus, these claims do not require any specific written description as to vaccines *per se*. Moreover, they are supported by, for example, Applicants' examples on pages 7-9, which compare the local reactions of submucosal and intramuscular administration for four different live bacterial strains.

IV. Response to the enablement rejection

Claims 6-20 have been rejected under 35 U.S.C. 112 (first paragraph) for lacking enablement. Specifically, the Office action indicates that Applicants' specification is not enabling as to methods using live vaccines generally. Applicants request withdrawal of this rejection.

Applicants believe that claims 6-20, as recited in their June 22, 2006 Amendment D, are enabled for the reasons stated in that amendment. Nevertheless, in an effort to expedite prosecution of this patent application, Applicants have amended claims 6, 7, 9, 11, 12, and 20 so that all of claims 6-20 now recite a live *attenuated* bacterial vaccine. Applicants make this amendment in accordance with the Examiner's comments on the top of page 6 in the September 11, 2006 Office action, which acknowledge that Applicants' specification enables the claimed methods using a live *attenuated* bacterial vaccine.

Applicants also submit that their specification provides sufficient written description for the subject matter recited in their new claims 21-28. Those claims do not specifically recite administration of a vaccine *per se*. Instead, they recite submucosal administration of live attenuated bacteria wherein any abscess and/or lesion formation at the site of the submucosal administration is less in total size than the abscess and/or lesion formation that

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would occur if the bacteria were instead administered intramuscularly or intradermally. Thus, these claims do not require any specific enablement as to preparing a vaccine *per se*.

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Applicants hereby request a three-month extension to respond to the September 11, 2006 Office action, and authorize the Commissioner to charge Deposit Account No. **02-2334** for the corresponding extension fee. In addition, Applicants authorize the Commissioner to charge Deposit Account No. **02-2334** for the fee corresponding to the claim fee for the two claims exceeding 20 in this latest amended claim set. Applicants do not believe that they owe any other fee in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **02-2334**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **02-2334**.

Applicants submit that the pending claims are in condition for allowance, and request that this application be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



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